BE IT KNOWN THAT I, TARNJIT SINGH GREWAL, of the County of Surrey, England, Notary Public duly authorised, admitted and sworn

DO HEREBY CERTIFY:

THAT on the 15th day of February I caused an inspection to be made at the EudraGMDP website (http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do0) and on the basis on such inspection **hereby certify as follows,**

THAT the document annexed hereto refers to The Manufacturer: **CAMBREX PROFARMACO MILANO S.R.L.** with Site Address: **Via Curiel, 34-20067 Paullo (MI), Italy**;

AND THAT the annexed **CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**, with Certificate No.IT-API/44/H/2019, is found at the above EudraGMDP website.

SIGNED AND SEALED at West Molesey, Surrey this fifteenth day of February in the year two thousand and twenty-one.

Protocol Number:
506293/28

Tarnjit Singh Grewal

Notary Public

GREWAL NOTARY

27 The Fairway
West Molesey, Surrey
KT8 1PB, England

+44 (0)20 8941 7360
grewalnotary.co.uk
notary@grewalnotary.co.uk

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: Pays / Pais:	United Kingdom of Great Britain and Northern Ireland
This public document Le présent acte public / El presente documento público	
2. Has been signed by a été signé par ha sido firmado por	Tarnjit Singh Grewal
3. Acting in the capacity of agissant en qualité de quien actúa en calidad de	Notary Public
4. Bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	The Said Notary Public

Certified

Attesté / Certificado

5. at á / en: London	**6. the** le / el día: 17 February 2021
7. by par / por	Her Majesty's Principal Secretary of State for Foreign, Commonwealth and Development Affairs
8. Number sous no / bajo el numero	APO-2241915
9. Seal / stamp Sceau / timbre Sello / timbre	**10. Signature** Signature Firma: S. Swift

FOREIGN, COMMONWEALTH & DEVELOPMENT OFFICE LONDON

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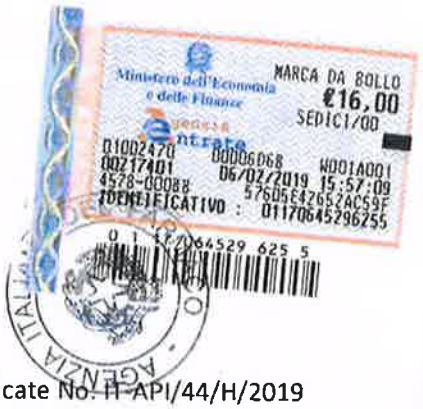

Certificate No: IT-API/44/H/2019

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:
The manufacturer CAMBREX PROFARMACO MILANO S.R.L.
Site address Via Curiel, 34 - 20067 PAULLO (MI)

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: **D.L. n. 219 of 24th April 2006 art. 53**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2019/01/31, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.
The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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GMP Inspections and Manufacturing Authorizations of APIs Office
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website: www.agenziafarmaco.it
SIS : 1751

Part 2

Name and address of the site:
CAMBREX PROFARMACO MILANO S.R.L. - Via Curiel, 34, 20067 PAULLO (MI)

Name of the active Substances manufactured or imported:

4-AMINO-6-CHLORO-1,3-BENZENEDISULFONAMIDE (DSA)
ACEBUTOLOL HYDROCHLORIDE
EPINEPHRINE
EPINEPHRINE BITARTRATE
ALOGLIPTIN BENZOATE
ALPRAZOLAM
AMBROXOL HYDROCHLORIDE
AMILORIDE HYDROCHLORIDE DIHYDRATE
AMIODARONE HYDROCHLORIDE
ARIPIPRAZOLE
BISACODYL
BREXPIPRAZOLE
BROMAZEPAM
BROTIZOLAM
CINACALCET HYDROCHLORIDE
CYSTEAMINE BITARTRATE
CYSTEAMINE HYDROCHLORIDE CRUDE
CLOBAZAM
CLONAZEPAM
DIPOTASSIUM CLORAZEPATE
CHLORDIAZEPOXIDE
CHLORDIAZEPOXIDE HYDROCHLORIDE
CHLORMADINONE ACETATE
CHLOROTHIAZIDE
CLOZAPINE
DIAZEPAM
DILTIAZEM HYDROCHLORIDE
DRONEDARONE
DRONEDARONE HYDROCHLORIDE

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ELETRIPTAN HYDROBROMIDE
ELTROMBOPAG OLAMINE
EMTRICITABINE
ERYTHROMYCIN
ERYTHROMYCIN LACTOBIONATE STERILE
ESTAZOLAM
ETIZOLAM
FLUCYTOSINE CRUDE
FLUNITRAZEPAM
FLURAZEPAM DIHYDROCHLORIDE
FLURAZEPAM MONOHYDROCHLORIDE
GLIBENCLAMIDE
GLIPIZIDE
GS-9674-02
HYDROCHLOROTHIAZIDE
LABETALOL HYDROCHLORIDE
LACOSAMIDE
LORAZEPAM
LORMETAZEPAM
MARAVIROC
MEDAZEPAM
METHYCLOTHIAZIDE
MIDAZOLAM
MIDAZOLAM HYDROCHLORIDE
MIDAZOLAM MALEATE
NITAZOXANIDE
NITRAZEPAM
NOREPINEPHRINE TARTRATE
ORCIPRENALINE SULFATE
OXAZEPAM
PARACETAMOL
PRANOPROFEN
PRAZEPAM
PROPAFENONE HYDROCHLORIDE
RALOXIFENE HYDROCHLORIDE
RALTEGRAVIR POTASSIUM
RANOLAZINE
RIFAXIMIN
RIVAROXABAN

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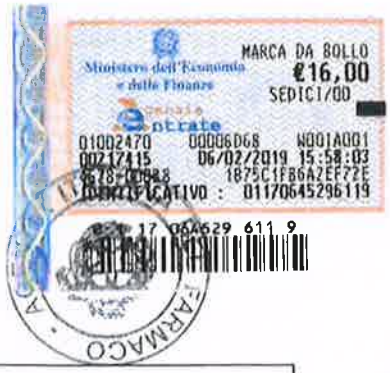
SALBUTAMOL CRUDE
SALBUTAMOL SULFATE
SODIUM CROMOGLICATE
SODIUM PICOSULFATE
SOLIFENACIN SUCCINATE
SOTALOL HYDROCHLORIDE
TEMAZEPAM
TERBUTALINE SULFATE
TERPIN HYDRATE
TOLTERODINE TARTRATE
TRIAZOLAM
TRIMETHOXYBENZENE
VILDAGLIPTIN
ZOLPIDEM TARTRATE

3. Manufacturing Operations - Active Substances

3 - Manufacturing Operations - Active Substances

ACEBUTOLOL HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation /Purification steps: salt formation, crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing



3 - Manufacturing Operations - Active Substances EPINEPHRINE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances EPINEPHRINE BITARTRATE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
ALOGLIPTIN BENZOATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
ALPRAZOLAM

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps:

	crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances **AMBROXOL HYDROCHLORIDE**	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

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	crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
AMBROXOL HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

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3 - Manufacturing Operations - Active Substances AMILORIDE HYDROCHLORIDE DIHYDRATE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: salt formation, crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances AMIODARONE HYDROCHLORIDE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
ARIPIPRAZOLE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
BISACODYL

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

	3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
BREXPIPRAZOLE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances BROMAZEPAM	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances BROTIZOLAM	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

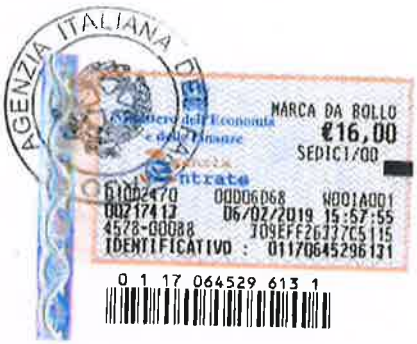
	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
CINACALCET HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling/micronisation 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
CYSTEAMINE BITARTRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance



	3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
CLOBAZAM

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances CLONAZEPAM	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances DIPOTASSIUM CLORAZEPATE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: salt formation, crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
CHLORDIAZEPOXIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
CHLORDIAZEPOXIDE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance

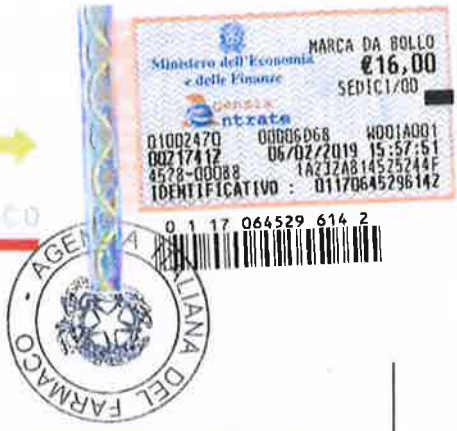
	3.1.3. Salt formation / Purification steps: salt formation,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
CHLORMADINONE ACETATE

3.5	**General Finishing Steps**
	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Special Requirements Other: Hormones or substances with hormonal activity
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
CHLOROTHIAZIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance



	3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary packagewithin an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
CLOZAPINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

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VI
GMP

3 - Manufacturing Operations - Active Substances DIAZEPAM	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealingthe active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances DILTIAZEM HYDROCHLORIDE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
DRONEDARONE (Confidential)

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying,milling,micronisation,sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1. Physical / Chemical testing

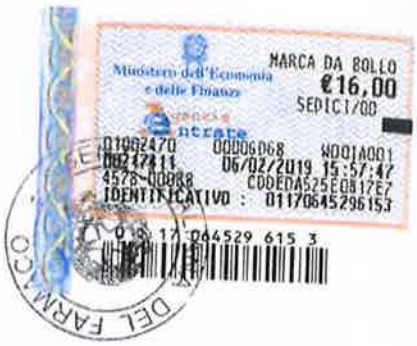
3 - Manufacturing Operations - Active Substances
DRONEDARONE HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

	3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
ELETRIPTAN HYDROBROMIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling/micronisation 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing



3 - Manufacturing Operations - Active Substances
ELTROMBOPAG OLAMINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
EMTRICITABINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an

	outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
ERYTHROMYCIN LACTOBIONATE STERILE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
ESTAZOLAM

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an

	outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
ETIZOLAM

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

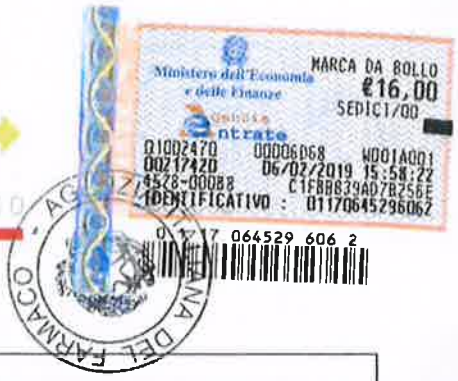
3 - Manufacturing Operations - Active Substances
FLUNITRAZEPAM

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps:

	crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
FLURAZEPAM DIHYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	**GeneralFinishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing



3 - Manufacturing Operations - Active Substances
FLURAZEPAM MONOHYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: salt formation, crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
GLIBENCLAMIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation/ Purification steps: salt formation, crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
GLIPIZIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
GS-9674-02 (Confidential)

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

	3.1.3. Salt formation / Purification steps: salt formation,crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

3 - Manufacturing Operations - Active Substances
HYDROCHLOROTHIAZIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purificationsteps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

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3 - Manufacturing Operations - Active Substances
LABETALOL HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
LACOSAMIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,milling,micronisation,sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
LORAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
LORMETAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
MARAVIROC

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying,sieving,milling/micronisation 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

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3 - Manufacturing Operations - Active Substances
MEDAZEPAM

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: salt formation, crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
METHYCLOTHIAZIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.2.** Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1.Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
MIDAZOLAM

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
MIDAZOLAM HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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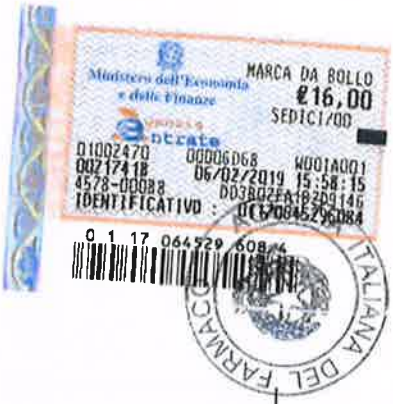

	3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances
MIDAZOLAM MALEATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

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	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

4. Other Activities - Active Substance:

Importation of:
4-AMINO-6-CHLORO-1,3-BENZENEDISULFONAMIDE (DSA) (Confidential); CYSTEAMINE HYDROCHLORIDE CRUDE (Confidential); ERYTHROMYCIN (Confidential); FLUCYTOSINE CRUDE (Confidential); PARACETAMOL (Confidential)

Restrictions or clarifying remarks:

For STERILE ERYTHROMYCIN LACTOBIONATE, sterile filtration and microbiological testing (including sterility testing) are outsourced. Manufactured APIs marked as confidential are for clinical use only.GS-9674-02:no batch certification.Imported APIs marked as confidential undergo further processing within the importing site. According to Italian regulation, all the sterile and/or of biological origin active substances listed in this document have undergone an authorization procedure. The Inspectorate adopted a risk-based approach for planning of inspections, therefore the validity of the GMP certificate for this manufacturing site is not more than 42 months from the last general GMP inspection, which was conducted on 2017/05/19. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.

Rome, 2019/03/05

Name and signature of the authorised person of the Competent Authority of Republic of Italy

Dott.ssa Marisa Delbò
AIFA - GMP Inspections and Manufacturing Authorizations of APIs Office

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